SEP - 6 2000

K001149

D. Substantial Equivalence

The Bair Hugger® Model 750 Total Temperature Management® system is substantially equivalent in safety and effectiveness to the predicate device, the Model 505 Total Temperature Management system (K960167), currently manufactured and marketed by Augustine Medical, Inc.

Bair Hugger Model 750 Warming Unit and Bair Hugger Model 505 Warming Unit

Summary of Similarities

- Both devices have the same intended use and patient populations.
- The Model 750 unit has similar mechanical characteristics; it uses the same type of heater and blower unit.
- The output temperature ranges at each temperature setting are the same (the tolerances are tighter on the Model 750 unit).
- The over temperature safety system provides visible and audible warnings.
- Both devices are designed for use with all of the current Bair Hugger blankets and the 241® fluid warming set. No modifications have been made to the blankets or the 241 set.
- Both warming units can be used as a shelf, floor or table model, or attached to an I.V. pole or bed rail. In addition, the Model 750 unit can be attached to a rack or stand.

Summary of Differences

- The Model 750 unit incorporates software as part of the primary temperature control system.
- The Model 750 unit provides greater airflow.
- The Model 750 unit measures the temperature at the distal end of the warming unit hose and displays it on the control panel; the Model 505 unit calculates this temperature. Because of this, the Model 750 unit uses a different warming unit hose.
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to 47 ± 2°C and the secondary over temperature sensor is set to 53 ± 3°C. The primary sensor for the Model 505 unit is set to 53 ± 3°C.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Device positioning	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole; or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail
Dimensions	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Weight	@12.5 lbs	@11.5 lbs.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every year	Every 6 months or 500 hours of use
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (at nozzle)	Ambient to 45 degrees	Ambient to 46 degrees
Heat generated	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Electrical requirements	20 Amp fused circuit	20 Amp fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Air filter	HEPA	0.2µM
Motor	40 watt DC	Fractional horsepower, single-phase, AC
Heater	1600W resistive	850W resistive
Leakage current	Meets requirements of UL 2601 and EN 60601-1	Meets requirements of UL 2601 and EN 60601-1
Power consumption at 20°C ambient condition	Peak: 1650W Avg.: 800W	Peak: 1000W Avg.: 450W
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician

Substantial Equivalence Table (cont.)

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Over temperature detection	Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47±2°C, measured at the end of the hose, plus an independent electronic system that reacts in the same manner and at the same set points as the SE device	Independent bulb and capillary. Thermal cutoff shuts the heater off at a preset high temperature of 53°C±3°C (127.4°F±3.6°F), measured at end of the hose.
Overcurrent protection	Dual input fused lines	Dual input fused lines
Alarm system	Over temperature: flashing red light with audible alarm, heater and blower shut down. Error condition: audible alarm, unit goes into *Standby* mode, error code displays in LCD window	Over temperature: flashing red light with audible alarm, heater shuts down.
Control circuitry	Microprocessor-based	Analog
Blankets Used	All Bair Hugger blankets (see next page for details)	All Bair Hugger blankets (see next page for details)
Blood/Fluid Warming System that can integrate with warming unit	Augustine Medical Model 241 system (see next page for details)	Augustine Medical Model 241 system (see next page for details)

Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734) ✓
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Augustine Medical
c/o David Westlin
Director of Regulatory Affairs and
Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
The Bair Hugger® Model 750 Total Temperature Management® System
Regulatory Class: II Two
Product Code: DWJ
Dated: July 19, 2000
Received: July 21, 2000

Dear Mr. Westlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger® Model 750 Total Temperature Management® System

Indications for use: The Bair Hugger® Model 750 Total Temperature Management® System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Bair Hugger® Model 750 Total Temperature Management® System should be used whenever conditions exist that could cause patients to become cold.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001149

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____
(Per 21 CFR 801-109)